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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/523,268	07/07/2005	John L. Schenk	XY-lowPressure-USNP	5591
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CR MILES P.C. 405 Mason Court, Suite 119 Fort Collins, CO 80524			EXAMINER NOBLE, MARCIA STEPHENS	
			ART UNIT 1632	PAPER NUMBER
			NOTIFICATION DATE 04/07/2010	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/523,268	Applicant(s) SCHENK ET AL.	
	Examiner MARCIA S. NOBLE	Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 8, 31, 39-52 and 62-72 is/are pending in the application.
- 4a) Of the above claim(s) 41-52 and 62-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 8, 31, 39, 40, 65-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 31 January 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/5/2010 has been entered.

Status of Claims

Claims 1-3, 8, 31, 39, 40-52, and 62-72 are pending. Claims 41-52 and 62-64 were previously withdrawn as non-elected subject matter in a restriction requirement. Claims 1-3, 8, 31, 39, 40 and 65-72 are under consideration.

Withdrawn Rejections

The rejection of claims 1-3, 8, 31, 39, and 40, under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement, is withdrawn. Applicant amended the claims to recite altering said flow characteristic...between about 30 psi and about 40 psi". This removes the possibility for two different flow characteristics and therefore the claims no longer encompass new matter.

The rejection of claims 1-3, 8, 31, 39, and 40, under 35 U.S.C. 112, second paragraph, as being indefinite for reciting "viability" and "cleavage rate", is withdrawn.

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Applicant amended the claims to recite, sperm cell viability and oocyte cleavage rate, which clarifies the claims.

The rejection of claims 1-3, 8, 31, 39, and 40, under 35 U.S.C. 112, second paragraph, as being indefinite for reciting, "altering flow characteristics of said fluid stream pressure to 30 psi and 40 psi", is withdrawn. Applicant amended the claims to recite altering said flow characteristics...to between about 30 psi and about 40 psi, which clarifies the claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 65-72, as amended or previously presented, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, as set forth in the Office Action, mailed 8/8/2008 (p. 6).

Claim 65 still recites, "viability" and "cleavage rate". These recitations are indefinite because it is unclear to what "viability" and "cleavage rate" are referring. It is recommended that Applicant amend the claims to recite, "sperm cell viability" and "oocyte cleavage rate", as was done for claim 1 and its dependents. This type of amendment should overcome the rejection.

In Applicant's remarks, filed 1/5/2010, Applicant asserts that the amendment to the claims would obviate this rejection. Applicant's argument is not found persuasive because claim 65 and its dependents still recite the indefinite recitation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3, 8, 33, and 65-69, as amended or previously presented, are rejected under 35 U.S.C. 102(b) as being anticipated by Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS).

Rath et al discloses a method of sorting sperm by sex and determining its ability to generate embryos by in vitro fertilization. Their method is comprised of collecting sperm from boars (p. 3347, col 2, par 1, line 1-2), subjecting the sperm to flow cytometry, and determining the generation of embryos produced by in vitro fertilization (a measure of fertility characteristics) with sex sorted sperm or unsorted sperm (p. 3348 in total). The flow cytometry consisted of generating a flow and entraining sperm samples into the fluid stream (p. 3348, col 1). They disclose that the fluid sheath was PBS (p. 3348, col 1). They disclosed that they adjusted the fluid stream flow through the adjustment of pressure to using high-speed sperm sorting with a fluid sheath

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pressure of 2.81 kg/cm², which is approximately 40 psi, to improve sorting and fertility characteristics over standard speed sorting (p. 3346, col 2, lines 3-7 and p. 3348, col 1). They disclosed that sperm motility following sorting was 60% in all cases (p. 3349, col 1). They also disclose fertilization rates and oocyte cleavage rates, which also indicates that the sperm is viable and can serve as a measure of sperm viability as claimed.

Response to Arguments

Applicant's arguments filed 1/5/2010 have been fully considered but they are not persuasive. Applicant asserts that the amendments to the claims to recite between 30 and 40 psi overcome the Rath rejection. It is noted Applicant did not explain why they believe such an amendment overcomes the art. Applicant's arguments are not found persuasive because Rath discloses a flow characteristic of about 40 psi. Therefore, Rath discloses the amended limitations of reciting a flow characteristic between 30 and 40 psi. Therefore, the amendments to the claims do not overcome the Rath rejection.

The following new objections and rejections are necessitated by amendments to the claims.

Claim Objections

Claims 1-3, 8, 31, 39, 40, and 65-72 are objected to because of the following informalities:

Claim 1, 65, and their dependent claims recite, "obtaining a sperm cell from a male of a species of mammal". The recitation of "a sperm cell from a male" is

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redundant because a sperm cell can only be obtained from a male. Amending the first step to recite, "obtaining a sperm from a mammal" would be remedial. It is recommended, but not required to remove the recitations of "of a species". This recitation does not add any breadth to the claims and makes the recited "obtaining" step cumbersome.

Claim 1 and its dependents recite, "generating....a sheath fluid selected from a group consisting of..." This recitation should be amended to recite, "generating...a sheath fluid selected from the group consisting of..." because "a group" suggests there are more than one possible group and there are no other possible groups from which to select.

Claim 1, 65, and their dependents recite, "selecting at least one desired sperm cell fertility characteristic, said at least one fertility characteristic selected from a group consisting of...". The recitations of "selected from a group consisting of" suggests that there are other possible groups to select from. However, no other groups exist in the specification. Amending the claims to recite, selecting at least one desired sperm cell fertility characteristic selected from the group consisting of...." would be remedial. It is also recommended to remove the recitations of, "said at least one fertility characteristic". This recitation is redundant, make the claim cumbersome, and difficult to follow.

Claims 2 and 66 recite "a species of mammal" numerous time. These recitations are redundant, do not further clarify such recitations as "bovine, equine, porcine", etc...,

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and make the claim cumbersome. Removing all the recitations of "a species of mammal" would be remedial.

Claims 3 and 67 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Independent claims 1 and 65 recite "generating a fluid stream...comprising a sheath fluid."

Dependent claims 3 and 67 further specify, "said fluid stream comprises a sheath fluid stream". However, as described above the independent claim already states that the fluid stream is a fluid sheath stream. Therefore, claims 3 and 67 are not further limiting.

Claims 8 and 69 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim.

Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 8 and 69 specifies that the fluid stream is generated by a flow cytometry or cell sorter. However, at the time of the invention, there was no other means of generating a fluid stream for subjecting sperm than use of a flow cytometry or cell sorter. Thus, the claim inherently is not further limiting. If Applicant can provide evidence that other means could have been used, the objection can be withdrawn. Otherwise, the claim should be cancelled.

At the end of the action in the Examiner's Comment section, an example of a possible claim amendment that would stream-line and clarify claim 1 is given.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall— conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 8, 31, 39, 40 and 65-72 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, 65, and its dependents recite, "oocyte blastocyst rate". This recitation is indefinite because oocytes do not have a "blastocyst rate". Embryos, fertilized oocytes, and zygotes form blastocyst, but oocytes do not. Amending the claims to solely recite "blastocyst rate" would overcome this limitation. An artisan would not understand what is meant by "blastocyst rate".

Claim 1, 65, and its dependents recite, "altering said flow characteristics of said fluid stream to adjust fluid stream pressure....". This recitation is indefinite because "altering" or "adjusting" the fluid stream pressure suggests that prior to this step some other fluid stream pressure has been designated. However, no such fluid stream pressure has been designated. It seems that Applicant may be choosing this language to try and suggest that different fluid streams are chosen for the fluid stream pressure depending upon the fertility characteristic desired. However, these recitations are not making this apparent. Below in the Examiner's comment, an example of a possible amendment for claim 1 has been provided that may clarify applicants intend for the claimed invention.

Claim 1, 65, and its dependent recites, "subjecting said sperm cell ...to said fluid stream". These claims then recite, "entraining said sperm cell into said fluid stream. These combined recitations are indefinite because it is not apparent how entraining the sperm samples differ from subjecting the sperm samples. These claims further recite, "controlling said ...sperm cell fertility selected through adjustment of said fluid stream. It is not apparent how the active "controlling" step differs from the combined altering and subjecting steps that precede the controlling steps. Amending the claims to remove the entraining and controlling steps would be remedial. See the example in the Examiner's comment for potential alternative language that will clarify these issues.

Claims 1, 65, and their dependents are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: collecting the sperm cells subjected to the fluid stream, thereby generating an insemination sample with a desired sperm cell fertility characteristic. The claims recite generation a sperm cell insemination sample that subjects the sperm to a fluid stream and does not necessarily collect the sperm subjected to the fluid stream. To obtain such an insemination sample the subjected sperm needed to be collected. Therefore, a collection step is required.

Claim 31 recites the limitation "said pregnancy rate of a female of said bovine species of mammal". There is insufficient antecedent basis for this limitation in the claim. The independent claim only recites a species of mammal. The independent claim never species bovine or pregnancy rate of a bovine. Thus, dependent claim 31

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lack antecedent basis. Claims 39 and 40 depend from claim 31 and thus are also indefinite.

Claim 31 recites, "wherein said pregnancy rate of a female of said bovine species of mammal inseminated with a bovine sperm cell insemination sample having controlled sperm cell fertility characteristics". This clause is incomplete. It defines a subject of the clause, "said pregnancy rate" but does not specify what happens to said pregnancy rate. The clause is at least missing a verb and possibly a direct object. Thus, the clause of claim 31 is incomprehensible and thus indefinite. Claim 70 has similar claim language as claim 31 except claim 70 recites, said pregnancy rate comprises a pregnancy rate...". If Applicant's intent is to further describe the pregnancy rate as is done in claim 70, amending the claim to have a similar recitation as that in claim 70 would be remedial. For art purposes, wherein clause of claim 31 is being interpreted as wherein the pregnancy rate comprises a pregnancy rate of a cow inseminated with a bovine sperm cell insemination sample having controlled sperm cell fertility characteristics, as is recite in claim 70.

Claim 1, 65, 31, 39, 40, and 70-72 recite, "sample having controlled sperm cell fertility characteristics". This recitation is indefinite because it is not apparent how the fertility characteristic is "controlled" in the sperm.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 31, 39, and 70-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rath et al (J Anim Sci 77:3346-3352, 1999; of record in IDS) in further view of Ax (US 4683213 patent date: 7/28/1997).

Rath teaches the claimed invention as discussed above. Rath does not explicitly teach that pregnancy rates obtained by inseminating cows with sperm from the insemination sample, as recited in claims 31 and 70. Further, Rath does not explicitly teach the insemination sample has the specified sperm cell concentrations, as specified in claims 39, 71, and 72. However, the limitations of these claims are not active method steps in the claims, thus implicitly the method taught by Rath should result in the pregnancy rates and sperm cell concentrations as claimed.

Rath does not teach that the method is used in a bovine. However, at the time the inventions was made methods for more easily predicting sperm fertility characteristics and sex characteristic in cattle were desired (see Ax col 1, line 14 to col 2, line 3). Therefore, it would have been obvious to an ordinary artisan at the time of filing to apply the method of Rath to bovine sperm with a reasonable expectation of success. Further an artisan would have been motivated to apply the method of Rath to bovine sperm because as taught by Ax traditional methods of determining fertility of bovine sperm are lengthy and time consuming and that methods that would more easily predict sperm fertility and sex in cattle would be beneficial.

The combination of prior art cited above in all rejections under 35 U.S.C. 103 satisfies the factual inquiries as set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). Once this has been accomplished the holdings in KSR can be applied (*KSR International Co. v. Teleflex Inc. (KSR)*, 550 U.S. 389, 82 USPQ2d 1385 (2007): "Exemplary rationales that may support a conclusion of obviousness include: (A) Combining prior art elements according to known methods to yield predictable results; (B) Simple substitution of one known element for another to obtain predictable results; (C) Use of known technique to improve similar devices (methods, or products) in the same way; (D) Applying a known technique to a known device (method, or product) ready for improvement to yield predictable results; (E) "Obvious to try" - choosing from a finite number of identified, predictable solutions, with a reasonable expectation of success; (F) Known work in one field of endeavor may prompt variations of it for use in either the same field or a different one based on design incentives or other market forces if the variations are predictable to one of ordinary skill in the art; (G) Some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention." In the present situation, rationales A, B, and G are applicable. The claimed method was known in the art at the time of filing as indicated by Rath and Ax. Thus, the teachings of the cited prior art in the obviousness rejection above provide the requisite teachings and motivations with a clear, reasonable expectation. The cited prior art meets the criteria set forth in both *Graham* and *KSR*.

Examiner's Comment

Example of a possible claim amendment that would clarify the claims is as follows:

Claim 1. A method of generating a sperm cell insemination sample, comprising: i) obtaining sperm cells from a mammal; ii) selecting at least one sperm cell fertility characteristic from the group consisting of sperm cell motility, sperm cell viability, oocyte cleavage rate, blastocyst rate, and pregnancy rate; iii) generating a fluid stream with a fluid stream pressure between about 30 and 40 psi depending upon the selected sperm cell characteristic(s), wherein if sperm cell motility is selected the fluid stream pressure is about 30 psi or about 40 psi, if sperm cell viability is selected the fluid stream pressure is about 30 psi or 40 psi, if oocyte cleavage rate is selected the fluid stream pressure is about 40 psi, if blastocyst rate is selected the fluid stream pressure is 40 psi, and if pregnancy rate is selected the fluid stream is 30 psi, and wherein said fluid stream comprises a fluid sheath selected from the group consisting of PBS, citrate buffer, 2.9% sodium citrate, HEPES buffer, TRIS-based sheath fluid, and a combination thereof; iii) subjecting said sperm cells to the generated fluid stream; and iv) collecting the sperm cells subjected to the generated fluid stream, thereby generating an insemination sample with a desired sperm cell fertility characteristic(s).

These claims amendments are recommended to clarify the claims and should overcome the objections and 112, 2nd paragraph rejections. These claim amendment do not address the prior art rejections.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARCIA S. NOBLE whose telephone number is (571)272-5545. The examiner can normally be reached on M-F 9 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272-4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Deborah Crouch/
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